Pansos

Pantoprazole

COMPOSITION

Pansos 20 Tablet: Each enteric-coated tablet contains Pantoprazole Sodium Sesquihydrate USP equivalent to Pantoprazole 20 mg.
Pansos 40 Tablet: Each enteric-coated tablet contains Pantoprazole Sodium Sesquihydrate USP equivalent to Pantoprazole 40 mg.

PHARMACOLOGY

Pansos (Pantoprazole) is a proton pump inhibitor that suppresses the final step in gastric acid production by covalently binding to the H^+/K^+ATPase enzyme system at the surface of the gastric parietal cell. This effect leads to inhibition of both basal and stimulated gastric acid secretion, irrespective of the stimulus that persists longer than 24 hours.

INDICATIONS

Pansos (Pantoprazole) is indicated where suppression of acid secretion has therapeutic benefit ; i.e
1. Peptic ulcer diseases
2. Gastro-esophageal reflux diseases
3. Ulcer induced by non-steroidal anti-inflammatory drugs (NSAIDs)
4. Eradication of *Helicobacter pylori* (in combination with antibiotics)
5. Zollinger-Ellison Syndrome

DOSAGE AND ADMINISTRATION

Benign gastric ulcer: 40 mg daily in the morning for 4 weeks, continued for further 4 weeks, if not fully healed.
Gastro-esophageal reflux disease: 20-40 mg daily in the morning for 4 weeks, continued for further 4 weeks, if not fully healed; maintenance dose is 20 mg daily, which may be increased to 40 mg daily.
Duodenal ulcer : 40 mg daily in the morning for 2 weeks, continued for further 2 weeks if not fully healed.
Duodenal ulcer associated with *Helicobacter pylori*: Pantoprazole is recommended at a dose of 40 mg twice daily in association with antimicrobial agents as detailed below :
Amoxicillin 1 gm and Clarithromycin 500 mg both twice daily for one week, or Clarithromycin 250 mg and Metronidazole 400 mg both twice daily for one week.
Prophylaxis of NSAID-associated gastric or duodenal ulcer: 20 mg daily for those require long-term NSAID treatment.
Zollinger-Ellison Syndrome: Initially 80 mg once daily adjusted according to response (elderly max. 40 mg daily); daily doses above 80 mg given in 2 divided doses.

CONTRAINDICATIONS

Pantoprazole is contraindicated in patients with known hypersensitivity to any of the components of the formulation.

WARNING AND PRECAUTION

Patients should be cautioned that Pantoprazole tablet should not be split, chewed or crushed. Long-term therapy of Pantoprazole may lead to malabsorption of Cyanocobalamin (Vitamin B_{12}) or may increase the risk of osteoporosis related disorders.

SIDE EFFECTS

Pantoprazole is well tolerated in both short-term and long-term treatment. Headache and diarrhea are the common side effects and rarely included side effects are abdominal pain, flatulence, rash, insomnia and hyperglycemia.

USE IN PREGNANCY AND LACTATION

US FDA pregnancy category of Pantoprazole is B. There are, however, no adequate and well-controlled studies in pregnant woman. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed. Pantoprazole has been shown to be excreted in human milk. So, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the benefit of the drug to the mother.

USE IN CHILDREN AND ADOLESCENTS

The safety and effectiveness of Pantoprazole for short-term treatment (up to eight weeks) of erosive esophagitis associated with GERD have been established in paediatric patients 1 year through 16 years of age. Effectiveness for erosive esophagitis has not been demonstrated in patients less than 1 year of age. In addition, for patients less than 5 years of age, there is no appropriate dosage strength in an age-appropriate formulation available. Therefore, Pantoprazole is indicated for the short-term treatment of erosive esophagitis associated with GERD for patients 5 years and older. The safety and effectiveness of Pantoprazole for paediatric uses other than erosive esophagitis have not been established.

DRUG INTERACTIONS

No significant drug interactions have been observed in clinical studies.

OVERDOSAGE

Experience in patients taking very high doses of Pantoprazole (> 240 mg) is limited. Spontaneous post-marketing reports of overdose are generally within the known safety profile of Pantoprazole. Pantoprazole is not removed by hemodialysis. In case of overdosage, treatment should be symptomatic and supportive.

STORAGE

Store below 30^{o}C temperature in a cool & dry place. Protect from light & moisture. Keep out of the reach of children.

HOW SUPPLIED

Pansos 20 Tablet: Each box contains 50 tablets in Alu-Alu blister pack.
Pansos 40 Tablet: Each box contains 50 tablets in Alu-Alu blister pack.

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NIPRO JMI Pharma

Manufactured by:
NIPRO JMI Pharma Ltd.
Chauddagram, Cumilla, Bangladesh.